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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/554,301	12/06/2006	Kenji Nakanishi	64353(70904)	6578
21874	7590	01/05/2009	EXAMINER	
EDWARDS ANGELL PALMER & DODGE LLP			MARTIN, PAUL C	
P.O. BOX 55874			ART UNIT	PAPER NUMBER
BOSTON, MA 02205			1657	
			MAIL DATE	DELIVERY MODE
			01/05/2009	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/554,301	NAKANISHI ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	PAUL C. MARTIN	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 01 December 2008.  
 2a) This action is **FINAL**.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-17 is/are pending in the application.  
 4a) Of the above claim(s) 1-10 and 14-17 is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 11-13 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on 24 October 2005 is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____ .
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>10/24/05, 2/23/06, 9/12/06, 11/30/06, 9/28/07</u> .	5) <input type="checkbox"/> Notice of Informal Patent Application
	6) <input type="checkbox"/> Other: _____



## **DETAILED ACTION**

Claims 1-17 are pending in this application.

### ***Election/Restrictions***

Applicant's election without traverse of Group IV (Claims 11-13) in the reply filed on 12/01/08 is acknowledged. Claims 1-10 and 14-17 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse.

Claims 11-13 were examined on their merits.

### ***Information Disclosure Statement***

The listing of references in the specification (Pgs. 4-6) is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892 or listed on a PTO-1449, they have not been considered.

***Claim Objections***

Claim 1 is objected to because of the following informalities: The term “*Staphylococcus aureus*” should be italicized. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 11 and 12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claims 11 and 12 are drawn to a method of inducing atopic dermatitis like symptoms in a model organism comprising the step of applying *S. aureus* derived Protein A (SpA) to the skin of the model organism. The method does not contain a step wherein the protective layer of skin is abraded or otherwise disrupted prior to application of the Protein A. White *et al.* teaches that unless skin is prepared by stripping with Sellotape no reaction is seen on intact skin of human volunteers (Pg. 44, Line 19).

Terada *et al.* teaches that application of SpA without prior treatment with SDS, a detergent used to destroy the skin barrier, no alterations in the skin of mouse model organisms were observed (Pg. 8816, Column 2, Lines 10-24). Therefore, unless some perturbation of the skin is performed concurrently or prior to application of Protein A, no inflammatory skin lesion would be expected to develop.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "like" in claim 1 is a relative term which renders the claim indefinite. The term "like" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The Claim refers to a model organism developing an inflammatory skin lesion like atopic dermatitis. It is unclear to what degree the skin lesion will resemble atopic dermatitis or whether atopic dermatitis itself actually develops in the model organism. Claims 12 and 13 are rejected as being dependent upon rejected Claim 11.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 11 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by *White et al. (1980)*.

*White et al.* teach a method wherein a vigorous inflammatory reaction is induced by applying *S. aureus* Protein A to the skin of human subjects, wherein the skin stratum corneum has been partially removed by tape stripping (Pg. 43, Lines 20-21 and Pg. 44, Lines 1-9 and 19-26).

It is inherent in the method of *White et al.* that the inflammatory skin lesions formed would be atopic dermatitis-like as the Specification defines an “inflammatory skin lesion like AD (atopic Dermatitis) as any immune disease which develop dependently on IL-18 and whose main symptom is inflammation on skin. As the method of *White et al.* results in a symptom of inflammation of the skin, it inherently meets the claim limitation.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 11-13 are rejected under 35 U.S.C. § 103(a) as being unpatentable over *White et al.* (1980) in view of *Tsai et al.* (2003).

The teachings of *White et al.* were discussed above.

*White et al.* does not teach wherein when Protein A is applied on the skin of a model organism, SDS is also applied.

*Tsai et al.* teaches wherein tape stripping and sodium dodecyl sulfate (SDS) are used as methods of permeability barrier (skin) disruption in mice (Pg. 170, Lines 1-10 and 39-46).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to modify the method of White *et al.* for inducing a vigorous inflammatory reaction by applying *S. aureus* Protein A to the tape stripped skin of human subjects by using SDS as the means of disrupting skin because both tape stripping and SDS application were art recognized techniques of disrupting skin for the purpose of experimental exposure to some agent. The MPEP states:

The selection of a known material based on its suitability for its intended use supported a *prima facie* obviousness determination in *Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327, 65 USPQ 297 (1945)

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PAUL C. MARTIN whose telephone number is (571)272-3348. The examiner can normally be reached on M-F 8am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Paul Martin  
Examiner  
Art Unit 1657

12/22/08

/JON P WEBER/

Supervisory Patent Examiner, Art Unit 1657